

EXHIBIT DX5

TO DECLARATION OF PETER J. GOSS IN
SUPPORT OF DEFENDANTS' OPPOSITION TO
PLAINTIFFS' MOTION TO EXCLUDE THE
OPINIONS AND TESTIMONY OF
JIM HO, PH.D

Terry Clyburn, MD – University of Texas Medical School of Houston

Air Barrier System. We know that the majority of prosthesis implant infections are colonized by skin bacteria such as *staphylococci* that protect themselves in biofilms and are becoming more resistant to antibiotic treatment. These bacteria are likely seeded into the incision site at the time of surgery. Anything that can be done to prevent initial bacterial intrusion of these organisms is highly desirable. People in the OR shed 10,000 skin particles per minute and studies show that bacteria on these particles of skin may cause surgical site infections after prosthesis implantation. Although not detectable by the human eye, these airborne particles can be present in significant numbers at the incision site, particularly when factoring in the numerous sources of air disruption in a busy operating room. Many common operating room dynamics create these disturbances. The opening and closing of doors, the choice of the ventilation systems, overhead operating room lights, anesthesia machines, portable x-ray machines, and most importantly room traffic and the movement of people. All of these disruptions cause the airflow patterns to become erratic potentially bringing high numbers of infectious causing bacteria in contact with the surgical site.

Gregory Stocks, MD – Fondren Orthopedic Group

The air barrier system creates a localized ultra clean cocoon over the surgical site that reduces the presence of particulate matter and microorganisms by up to 84 percent. It is easy to apply and does not impede surgical conduct. Unlike laminar air handling systems for an entire room, the ABS controls the environment right at the incision site. Airborne contamination due to the people and room dynamics are taken out of play. The ABS consists of two major components. A non-sterile filter unit and a sterile air delivery nozzle. The Hepa filter unit which is mobile is incased in a steel cabinet for low maintenance and provides a quiet and efficient ultra clean air source. The ABS nozzle comes sterilized in double peel packages and the flexibility of the hose allows the nozzle to be easily positioned over multiple areas on the patient. When attached to the filter unit the nozzle produces a gentle non-turbulent flow of air over the surgical site. A quick locking mechanism allows efficient connection to the filter unit. A hook and loop pad with adhesive backing is applied to the incision drape either proximally or distally and within 5 centimeters of the incision site. The nozzle is then pressed onto the pad facing the incision site and is held securely. If required the nozzle can be easily removed and repositioned. This flexibility allows the ABS to successfully maintain protection of the surgical site while allowing for a full range of motion and minimal interference with instruments during a procedure. The clean air cocoon produced by the ABS creates a protective environment of 6 by 20 inches with a 2 inch depth. Particle counter analysis shows that a surgical incision environment may contain many thousands of bacteria carrying particles per cubic meter. As the ABS airflow is turned on the system aggressively reduces the particles count and presence of microorganisms by over 84 percent. The ABS accomplishes this even during highly dynamic procedures such as hip arthroplasty. By effectively shielding the incision site, the presence of potentially infection causing organisms is greatly reduced.



Brian Parsley, MD – Health Policy Committee Chairman, AAHKS

We know that the rate of prosthetic joint infections is rising even as the total number of procedures is increasing. More frequently observed patient factors such as diabetes and obesity make it difficult for patients to fight off bacterial intrusions. Prosthetic infections are devastating to patients and represent an enormous cost burden. Here is what we know; infections have a profound effect on patients. Infections are costly and CMS is requiring infections to be reported and is pushing the cost of treating infections back to institutions and physicians. And lastly, insurance providers are likely to follow suit. We should be doing everything we can to minimize the risk represented by airborne bacteria and other vectors of infection. The air barrier system is an effective way to accomplish this task. Nimbic Air Barrier System, the superior surgical environment.